REMARKS

Claims 1-9, 12-18, 22-29, 31-40, 58, 59, 67, 68, 70-90 and 92-104 are pending in the application, claims 92-104 being newly added and claims 19, 69 and 91 being canceled herein. Claims 10, 11, 20, 21, 30, 41-57, and 60-66 were previously canceled. Claims 1, 29, 58, 68, 70, 72, 73, 78, and 90 are the only independent claims.

The Specification

The specification has been amended to provide clear antecedent support for new claim language introduced herein (e.g., claim 73). This new claim language finds support in applicant's specification at page 15, first full paragraph.

Claims Rejections - 35 U.S.C. § 112, First Paragraph – Written Description

Claims 1-9, 12-19, 22-28, 67, 82, and 84 stand rejected under 35 U.S.C. § 112, first paragraph, as being failing to comply with the written description requirement. The Examiner maintains that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner in particular contends that the condition of being "effectuated in the absence of any visible undesirable condition" in claim 1 is new matter. The Examiner also contends that the condition of "prior to detecting any substantial visible change" is new matter, not provided in the original disclosure.

Applicant respectfully traverses the rejection of claims 1-9, 12-19, 22-28, 67, 82, and 84 under 35 U.S.C. § 112, first paragraph. While the phrases "in the absence of any visible undesirable condition" and "prior to detecting any substantial visible change" were not in the original specification, the substance of this language and the underlying

invention are indeed conveyed in applicant's original disclosure. One of ordinary skill in the art would certainly understand from applicant's original disclosure that applicant had possession of the invention as set forth in claims 1-9, 12-19, 22-28, 67, 82, and 84.

Applicant's invention concerns the application of light energy or electromagnetic radiation to skin surfaces to treat the skin to promote and/or protect the health of the skin and underlying tissues. The invention provides a method for treating skin as a prophylactic measure. (See the Objects of the Invention in the original specification.) In contrast to prior art uses of pulsed light energy (e.g., Eckhouse), applicant's pulsed light energy does not damage any skin structures (see second paragraph of applicant's Summary). Thus, applicant's method does not affect the short-term appearance of the target skin surface (Eckhouse's method removes hair).

It cannot be disputed that the invention applies, *inter alia*, to the treatment of skin that is normal and healthy – that is, without visible undesirable conditions. It would not make sense for the invention to apply only to skin with visible undesirable skin conditions, since the purpose of the invention is to avoid development of at least certain kinds of visible undesirable skin conditions – namely those resulting from overexposure to ultraviolet and/or X-ray radiation.

As stated in applicant's original disclosure, "the present invention is directed to the preclinical treatment of skin as a prophylactic measure against potential Xray or ultraviolet radiation damage" (paragraph 0019 of the published application) and "[t]he radiation is applied as a prophylactic or preventative measure to obviate any possible Xray or ultraviolet radiation damage that might otherwise occur because of exposure to

the sun or other source of Xray or UV radiation" (paragraph 0030 of the published application).

In view of such passages, one of ordinary skill in the art would have immediately understood that applicant's invention is of ***particular benefit*** to treat skin without any visible undesirable condition – for prophylaxis purposes. One of ordinary skill in the art would also have understood this to be within applicant's original intent and purpose – to treat skin that has no visible undesirable condition, to prevent (prophylaxis) a particular kind of undesirable condition, damage from ultraviolet and/or X-ray radiation. It would not have made sense to one of ordinary skill in the art that applicant's invention would be used only with skin having one or more visible undesirable conditions.

The clause "prior to detecting any substantial visible change" in claim 1 evidently implies that there is eventually substantial visible change in the skin surface which is under treatment. That implicit meaning is outside of applicant's disclosure in that applicant's method is intended to reduce the incidence or likelihood of skin damage and thus the likelihood that there would be any substantial visible change. Rather, it is accurate and consistent with applicant's original disclosure to say that further treatments as per claim 1 are effectuated without detecting any visible change. Claim 1 has been so amended. It is clear from applicant's original disclosure that applicant contemplates multiple skin treatments with electromagnetic radiation as a prophylactic measure. "Prophylactic" means that the ***damage that would otherwise occur is avoided***. Concomitantly, there is no substantial visible change in the skin surface because the damage that would give rise to such change is avoided, reduced, prevented, obviated, or blocked.

Claims Rejections - 35 U.S.C. § 112, First Paragraph – Enablement

Claims 1-9, 12-19, 22-29, 31-40, 67-80, and 82-89 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner maintains that the claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. According to the Examiner, the disclosed and claimed methods cannot be easily replicated without undue experimentation. Specifically, the Examiner contends that applicant has not provided an enabling disclosure which would permit one to practice the invention to at least "reduce damage" to the skin. The claim language leads one to believe that the damage already experienced is somehow reduced or reversed. Also, the Examiner contends that there is no evidence to support a reduction or prevention of damage.

In response to these allegations of the Examiner, applicant notes the following:

(1) Applicant's methods can be easily replicated without undue experimentation because the experimentation necessary for one of ordinary skill in the art to carry out applicant's methods is well within the degree of experimentation customarily exercised by those in the field. As discussed in greater detail below, the very prior art cited by the Examiner demonstrates that the range of parameters for those working in this field is characteristically very broad. Accordingly, the degree of experimentation required for one of ordinary skill in the art to follow applicant's teachings is ***not undue*** experimentation.

(2) Applicant has amended the relevant claims to change the phrase "reduce damage" to the phrase "reduce the incidence or likelihood of damage." Accordingly, the

claim language no longer "leads one to believe that the damage already experienced is somehow reduced or reversed." Support for this language is found in paragraph 0109 of the published application.

(3) With respect to evidence to support a reduction or prevention of damage, applicant reasserts the arguments made in a previous Amendment in response to the Examiner rejection of the claims under Section 101 of the Patent Statute. The Examiner is attempting to disguise his prior utility rejection as an enablement issue.

In further response to the Examiner's contention that there is no evidence to support a reduction or prevention of damage, applicant encloses herewith copies of journal articles that provide evidence to support a reduction or prevention of damage. The articles are discussed below (section B).

The Examiner cites, from MPEP § 2164.01(a), the following factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

(A) The breadth of the claims. The Examiner points out that the applicant cites fluences from 0.01 Joules/ cm^2 to 200 Joules/cm^2 and implies that this range is enormous by contending that the upper and lower limits differ by a range factor of 10,000. This implication is specious and inapposite. Applicant's range is less than 200 Joules. If applicant had instead cited a range of less than 200 Joules or from 0 Joules/cm^2 to 200 Joules/cm^2, would the Examiner have said that applicants' upper and lower limits differ by an infinite factor? U.S. Patent No. 6,676,655 to McDaniel, cited by the Examiner,

recites and claims fluences of less than 10 Joules/cm^2. The upper and lower ends of this range differ by an infinite factor.

Applicant's fluence range is no greater and substantially less than ranges typically taught by patentees in this field. McDaniel, for instance, teaches other ranges that are substantially broader than applicant's: pulse durations of from about 0.1 femtoseconds to about 100 seconds (compare to applicant's 1 msec and 2 sec); an interpulse delay between about 0.1 to about 1000 milliseconds (compare to applicant's 1 msec and 500 msec); and an energy spectrum of multichromatic electromagnetic radiation having a dominant emissive wavelength of from about 300 nm to about 1600 nm (compare to applicant's range of UV -- about 200 nm -- to about 1200 nm). McDaniel's disclosure is representative of disclosures in the field of therapeutic or cosmetic application of radiant or electromagnetic energy to skin surfaces. The prior art thus provides substantial evidence that the level of skill in this art is such that one of ordinary skill in the art would have no difficulty in carrying out applicant's invention without experimentation that would be undue in this field of endeavor.

Moreover, applicant teaches that the less the energy applied (the lower the fluence of a light pulse sequence), the safer it is for the patient/client or home user of applicant's method. Thus one of ordinary skill in the art is naturally guided by applicant's disclosure to lower energy ranges. Applicant teaches in Paragraph 0166 of the published application, for example, that applicant's invention

> allows for multiple passes over any particular skin surface. The selected light treatment parameters may be the same for each pass or may vary from pass to pass. In addition, the passes may follow immediately after one another or may be spaced by an interval during which, for instance, the light treatment device is used to apply light pulses to another area of the user's skin. An advantage of multiple passes is that the total power applied to a given skin surface may be reduced

> relative to that needed for accomplishing the desired prophylactic treatment by a single pass. For example, instead of a single pass of 50 Joules/cm^2, skin could be effectively treated by two passes of 20 Joules/cm^2 apiece. If the number of passes is increased further, the total power may be reduced even more. For instance, twenty passes may require a power no greater than 0.01 Joule/cm^2.

Accordingly, although applicant claims a fluence range of 200 Joules/cm^2, applicant provides plenty of teaching to guide one of ordinary skill in the art to a small part of that cited range of energies. This guidance provides enablement to those skilled in the art.

(B) The nature of the invention. The Examiner maintains that applicant's method results are based on speculation with no experimental evidence of prior art to validate any operational parameters.

Applicant respectfully traverses the Examiner's characterization of the nature of the invention. The Examiner is again trying to disguise a utility rejection as an enablement rejection. Applicant has previously explained how a utility rejection is inapposite to this application.

As discussed hereinabove, the nature of applicant's invention is characteristic of inventions in the field. Those of ordinary skill in the art are accustomed to and expect a degree of experimentation with operational parameters.

Applicant's invention is not based on speculation but arises from applicant's considerable experience in the field of cosmetic and therapeutic dermatology. Applicant has clinical evidence that the application of pulsed light energy to skin has substantial health benefits. In response to the Examiner's allegations, applicant has again searched the literature and found journal articles (copies enclosed) that support and confirm his observations as embodied in the present invention. For instance, Menezes, S. et al.,

"Non-coherent near infrared radiation protects normal human fibroblasts from solar UV toxicity," *Journal of Investigative Dermatology*, 1998 Oct; 111(4)-629-33, found the "induction by non-coherent IR radiation (700-2000 nm), in the absence of rising temperature, of a strong cellular defense against solar UV cytotoxicity as well as induction of cell mitosis."

Discussion of other journal articles evidencing the therapeutic effect of low-dose electromagnetic radiation treatment follows.

Maeda, T., Chua, P. P., et al., "Nucleotide excision repair genes are up-regulated by low-dose artificial UVB: evidence of a photo-protective SOS response?" *Journal of Investigative Dermatology,* 2001: 117: 1490-1497, found that nucleotide excision repair is induced in cells exposed to lower doses of UVB, which may protect damaged keratinocytes from cell death. Maeda et al. used a radiation fluence of 100 joules per m^2 (.01 joules per cm^2) as an effective "low dose" of UVB radiation.

Latonen, L., Taya, Y., "UV radiation induces dose-dependent regulation of p53 response and modulates p53-HDM2 interaction in human fibroblasts," *Oncogene* (2001): 20: 6784-6793, "found that low doses of UV radiation (UV B/C) induced a rapid p53 accumulation followed by a decrease which correlated with a transient cell cycle withdrawal and presumably also DNA repair."

According to Li, G., Ho, V. C., "p53-dependent DNA repair and apoptosis respond differently to high- and low-dose UV radiation," *British Journal of Dermatology*, 1998; 139:1-10, "... our data support the notion that p53 is a guardian of the genome. p53 participates in both repair of UV-damaged DNA and the induction of apoptosis. When

cells are exposed to low doses of UV radiation, the moderate induction of p53 upregulates NER and p21 which initiates cell cycle arrest to allow DNA repair."

The above articles predate applicant's filing date. Subsequent investigations provide further confirmation of applicant's method results.

Frank, S., Menezes, S., et al., "Infrared radiation induces the P 53 signaling pathway: role in infrared prevention of UVB toxicity," *Experimental Dermatology*, 2006: 15: 130-137, state that "IR radiation seems to induce the same UVB-regulated targets involved in the P 53 signaling pathway and could thus prepare cells to resist and/or repair further damage." Also, "IR pre-irradiation reduces UVB-induced thymine dimer formation."

Daniel Barolet et al. in U.S. Patent Application Publication No. 2006/0173512 disclose a method for protecting mammalian skin against photodamage caused by an exposure to a damaging radiation. The method includes irradiating the mammalian skin with a protective radiation before the exposure to the damaging radiation, the protective radiation including radiation having a wavelength larger than the wavelength of the damaging radiation, the protective radiation being irradiated onto the mammalian skin under conditions suitable for reducing photodamage to the mammalian skin caused by the damaging radiation. More particularly, Barolet et al. disclose a wavelength of 660 nm and fluences of between 2 and 10 Joules/cm^2.

In a related vein, M. Maitland LeLand et al., "Treatment of Radiation-Induced Dermatits with Light-Emitting Diode (LED) Photomodulation," *L:asers in Surgery and Medicine.* 39:164-168 (2007), found that the incidence of radiation dermatitis induced by cancer radiation therapy on breast tissues could be alleviated by the application of light

energy using an LED source immediately after the radiation therapy. The LED light was administered at a preset cycle, 590 nm, 100 pulse, 200 msec per pulse at a fluence of 0.15 J/cm^2 within one hour after the radiation therapy.

A summary of recent investigation in the field is provided by Verschooten, L., Claerhout, S., et al., "New Strategies of Photoprotection," *Photochemistry and Photobiology*, (2006) 82:4, 1016:

> "Recent studies investigated the influence of near infrared (IR) pre-irradiation on the UV-response. It was found that pre-exposure of human fibroblast to IR prevents UV-induced cytotoxicity and prevents apoptosis by influencing the mitochondrial apoptotic pathway. IR leads to an at least partially p53-dependent adaptive response resulting in a reduction of UV-induced thymidine dimers. Thus, in addition to UV, IR irradiation also appears to be capable to induce an adaptive response"

(C) The state of the prior art. The Examiner points out that no prior art has been presented that suggests that radiation of tissue may prevent or reduce damage due to subsequent X-ray or ultraviolet radiation.

The Examiner appears to be saying here that applicant's invention is not enabled because the invention is not found in the prior art. If applicant's invention were found in the prior art, would applicant have made an invention?

As demonstrated by U.S. Patent No. 6,676,655 to McDaniel and the above-discussed journal articles, the state of the prior art is such that one of ordinary skill in the art would have been able to make and use applicant's invention without undue experimentation.

(D) The level of one of ordinary skill in the art. According to the Examiner a skilled artisan, being aware of the impact of radiation parameters on the fluence delivered

and that skin varies from person to person, would inherently have to experiment to determine the best method based on tissue variables and radiation parameters.

The Examiner has misstated the law here. The question is not whether those skilled in the art would have to experiment. Rather, the question is whether one skilled in the art attempting to carry out applicant's invention would have to engage in an ***undue*** amount of experimentation. As indicated above, the field of applicant's invention necessarily involves a certain degree of experimentation. Applicant has provided sufficient guidance, relative to that normal in the field, so that one of ordinary skill in the art would not have to engage in an undue amount of experimentation.

It is to be noted as well that the level of skill in this art is fairly high. The Examiner does not address this fact. The present practitioners are licensed and board certified dermatologists with years of practice in the application of light energy (for instance, to remove blood vessels and hair). Such physicians would not be encumbered by, but on the contrary would be assisted by, applicant's disclosure to provide beneficial treatment to patients who are subject to significant degrees of solar radiation and other sources of UV and Xray waveform energy.

(E) The level of predictability in the art. The Examiner maintains that there is no perceived predictability because of the lack of prior art or clinical results.

Applicant cites journal articles and the published Barolet application above that support the method results he claims. These publications evidence results pursuant to applicant's descriptions, using experimental parameters well within applicant's claimed ranges and close to applicant's guidelines. The level of predictability in the field is not

such that one of ordinary skill in the art would have to engage in undue experimentation to carry out applicant's method. See discussion above with respect to factors B and D.

(F) The amount of direction provided by the inventor. As discussed above, applicant's parameter ranges are not broad relative to parameter ranges characteristic in the field of therapeutic and cosmetic application of light to skin surfaces. As further discussed above, applicant has provided direction with respect to the minimization of applied energy in carrying out the method of the present invention. The amount of direction provided by applicant is considered adequate given the nature of the field and the level of skill in the art.

(G) The existence of working examples. Applicant has provided concrete examples, all with fluences well within in the lower half of applicant's claimed range. Moreover applicant has indicated that multiple passes of lower radiation fluence is most beneficial to carrying out the invention. These teachings suitably direct one skilled in the art.

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. For reasons discussed above, applicant strongly contravenes the Examiner's conclusion that the level of experimentation required to carry out applicant's invention is greater than that allowed by current law. One skilled in the art would not have to engage in undue experimentation. The level of skill in the art is unequivocally high. Applicant has provided direction, examples, and theories as to cellular and molecular mechanisms. Those skilled in the art are accustomed to and expect a degree of experimentation inevitable with individuals having a broad range of skin colors and sensitivities to radiation, both pulsed and natural.

Claims Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 1-9, 12-19, 22-28, 67-69, 84, and 86 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner specifically maintains that the term "visible undesirable condition" is indefinite, requires a subjective judgment, leading one not to be precisely aware of the metes and bounds of the patient protection desired. What is undesirable for one person may be undesirable to another person.

Applicant respectfully traverses this rejection of claims 1-9, 12-19, 22-28, 67-69, 84, and 86 under 35 U.S.C. § 112, second paragraph. One skilled in the relevant art – the therapeutic and cosmetic application of light energy to skin surfaces – is certainly well apprised of what constitutes visible undesirable skin conditions. In the field of dermatology, there is an accepted and well-known convention of what are undesirable skin conditions. The prior art relied on by the Examiner evidences such knowledge and convention. U.S. Patent No. 6,514,243 to Eckhouse et al. states at col. 8, line 25, "To treat a skin (or visible) disorder a required light density on the skin must be delivered." As quoted in U.S. Patent No. 6,017,360 to Chubb et al., "There are certain skin conditions in which the application of ultraviolet radiation may lead to an exacerbation. These include the acute onset of psoriasis, acute eczema, lupus erythematosus, herpes simplex, and xeroderma pigmentosum." Dermatologists are certainly in agreement as to what constitutes undesirable skin conditions, including xerosis (dry skin) at one end and melanomas at an opposite end of a spectrum of seriousness.

Claims 1, 68, 72, and 73 and their dependent claims are purportedly indefinite due to a cited result of reducing damage to skin, implying that the skin is damaged, while requiring no visible undesirable condition prior to treatment.

In response to this rejection of claims under 35 U.S.C. § 112, second paragraph, independent claims 1, 68, 72 and 73 have been amended to change the phrase "reduce damage" to the phrase "reduce the incidence or likelihood of damage." The change finds support in the specification as noted above and avoids the apparent discrepancy referred to by the Examiner.

Claim 18 is cited by the Examiner as being indefinite as to the meaning of the phrase "further removed in time."

In response to the Examiner's citation of claim 18, that claim has been amended to provide an alternate description of the subject matter therein claimed. It is believed that the amended language clarifies the meaning of the claim.

The Examiner points out that the limitation "the occasions" in line 1 of claim 19 has insufficient antecedent basis in the claim.

In response to the Examiner's point about claim 19, that claim has been canceled.

Claim Objections

The Examiner objects to claims 84-89 as being of improper dependent form for failing to further limit the subject matter of a previous claim.

In response to the objection to claims 84-89, applicant has amended those claims to place them in proper dependent form. The subject matter of these claims is now in the form of additional positively recited method steps.

Claims Rejections - 35 U.S.C. §§ 102 and 103

Claims 70-75, 87 and 88 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,017,360 to Chubb et al. ("Chubb").

Claims 1-9, 12-19, 24, 29, 31-37, 40, 67-69, 78-80, 84-86 and 89 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chubb in view of U.S. Patent No. 6,514,243 to Eckhouse et al. ("Eckhouse").

Claims 22, 23, 38, and 39 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chubb in view of Eckhouse and further in view of Talpalriu et al. (Talpalrui").

Claims 25-28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chubb in view of Eckhouse and further in view of U.S. Patent No. 6,676,655 to McDaniel.

Claims 58 and 59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Talpalriu.

Claims 76 and 77 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chubb.

Claim 81 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Talpalrui in view of U.S. Patent No. 6,730,113 to Eckhardt et al. ("Eckhardt").

Claims 82 and 83 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chubb in view of Eckhouse in view of Talpalrui and further in view of Eckhardt.

Claims 90 and 91 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Talpalrui and in view of Eckhardt.

The Invention Applicant's invention pertains to a prophylactic method of applying electromagnetic radiation to skin surfaces to reduce, if not eliminate, the incidence or likelihood that those skin surfaces will be damaged by exposure to a source of Xray or ultraviolet radiation. **None of the prior art references relied on by the Examiner say anything whatsoever about such a *prophylactic* application of electromagnetic radiation.**

Pursuant to applicant's method, electromagnetic radiation is applied to a skin surface in the absence of any visible undesirable skin condition and more particularly in the absence of any damage from ultraviolet or X-ray radiation. The parameters of the applied electromagnetic radiation are so selected that there is no damage to the skin and that the incidence or likelihood of skin damage from exposure to UV or X-ray radiation is reduced. Applicant's prophylactic radiation may be applied before, during or after the exposure to potentially damaging UV or X-ray radiation (but should be applied within a predetermined interval of the potentially dangerous exposure).

Contrast to the Prior Art None of the prior art references relied on by the Examiner in rejecting the claims of the present application contemplates the application of electromagnetic radiant energy to a skin surface as a prophylactic measure to reduce the incidence or likelihood of damage to the skin caused by exposure to X-ray or ultraviolet radiation. Applicant's method provides a substantial health benefit to people of all ages that the cited prior art does not provide.

None of the references relied on by the Examiner is directed to or suggests the application of electromagnetic radiation to a skin surface in the absence of any visible undesirable skin condition and more particularly in the absence of any damage from

ultraviolet or X-ray radiation, where the parameters of the applied electromagnetic radiation are selected to reduce the incidence or likelihood of skin damage from exposure to UV or X-ray radiation and so selected that there is no damage to the skin.

Preferably, applicant's method utilizes pulsed electromagnetic radiation. Applicant's pulsed radiation is not designed to treat skin disorders and is typically applied in the absence of any visible undesirable skin condition. In contrast, in the prior art, pulsed light is used to treat visible skin disorders and other visible undesirable skin conditions, such as unwanted hair. See the Eckhouse (col. 1, line 36 et seq.; col. 21, lines 19-27) and McDaniel (abstract) references.

Applicant's pulsed radiation does not cause any damage to skin structures. In contrast the prior art teaches the use of pulsed radiation to ***damage*** skin structures. Eckhouse, for example, teaches the destruction of hair follicles (col. 1, line 36) and blood vessels (col. 21, lines 21 et seq.).

In short, the prior art teaches the application of pulsed radiation to damage targeted microscopic skin structures for purposes of treating visible undesirable skin conditions, while applicant teaches the application of pulsed radiation to reduce the likelihood or incidence of skin damage by UV or X-ray radiation, where there is no visible radiation damage and where the pulsed radiation causes no damage to skin structures.

Differences Between the Invention and Chubb Reference Pursuant to applicant's invention, the more exposure that the individual has to potentially harmful radiation (such as sunlight), the more the electromagnetic radiation that is applied to the individual's skin as a prophylactic measure. Applicant's method applies ***increasing***

amounts of radiation with ***increasing*** exposure of the individual to potentially harmful radiation such as sunlight.

In contrast with applicant's invention, Chubb, the primary reference relied on by the Examiner in rejecting applicant's claims, applies ***increasing*** amounts of radiation with ***decreasing*** exposure of the individual to sunlight. Thus, during the winter, when there is little exposure of the individual to sunlight and particularly UVB radiation (trigger for vitamin D production), Chubb's method dictates an ***increase*** in exposure to sources of UVB radiation, while applicant's method contemplates a ***reduction***, if not a cessation, in the application of electromagnetic radiation. Concomitantly, during the summer, when there is significant exposure of the individual to sunlight and particularly UVB radiation, Chubb's method dictates a ***decrease*** in, or cessation of, exposure to additional or artificial sources of UVB radiation, while applicant's method requires a much ***increased*** application of electromagnetic radiation.

Someone who spends a lot of time indoors will receive a lot of light treatment under the method of Chubb and no treatment under applicant's method (assuming no UV tanning lamps and other sources of UV or X-ray radiation indoors).

The opposing requirements of applicant's method and Chubb's method arise from the different objectives of applicant and Chubb et al. Applicant contemplates a prophylactic application of electromagnetic radiation to reduce the incidence or likelihood of skin damage due to exposure to UV and Xray energy. Chubb is interested in achieving an even distribution of UVB exposure over the course of a year to ensure continuously suitable amounts of vitamin D production. Chubb does not attempt to counteract or reduce the effect of UV and X-ray radiation on the skin. (Chubb maintains

that having an even distribution of UVB exposure during the year will lessen the likelihood of developing skin cancer.)

Chubb regulates overall exposure to UVB radiation. Applicant does not regulate exposure to UVB (and/or X-ray) radiation but rather applies preferably pulsed radiation at preferably low fluence levels to moderate the effects of the exposure.

Applicant's method changes the body's response to ultraviolet radiation and more particularly raises the MED level, with a consequence of less redness and irritation from the same amount of sun exposure. Chubb varies the exposure to UVB radiation so that it is below the natural MED for an individual.

The lack of overlap between applicant's method and Chubb may be seen in the fact that applicant's method could be beneficially used in conjunction with the methods of Chubb to reduce potential damage to the skin caused by that prior art method.

The difference between applicant's method and that of Chubb is also apparent upon considering that Chubb requires more UVB for darker complexions (see col. 17, line 28-32), while applicant provides for reduced treatment for darker complexions (see applicant's disclosure page 17, last 3 lines; page 19, line 6; page 27, line 7).

In introducing Chubb on page 2 of the Office Action, the Examiner states that "any skin condition may be present at the exposure" in the method of Chubb. This is not true. Chubb particularly points out that the patient's skin must be examined inasmuch as there are certain skin conditions that should not be exposed to UVB radiation. As set forth in col. 22, lines 40 et seq., of the Chubb reference, "There are certain skin conditions in which the application of ultraviolet radiation may lead to an exacerbation.

These include the acute onset of psoriasis, acute eczema, lupus erythematosus, herpes simplex, and xeroderma pigmentosum."

The Examiner also states, in the Response to Arguments section of the Office action (page 2), that a "determination of exposure is inherently done in the evaluation of vitamin D needs of an individual." This statement is also untrue. As discussed in greater detail below, an individual's complement of vitamin D is determined by UVB exposure ***and by diet***. The individual's vitamin D needs further depends on his or her consumption of vitamin D supplements.

Applicant discusses his independent claims below and points out further differences between the invention and the prior art as cited and relied upon by the Examiner.

Claim 1 As set forth in claim 1, a skin treatment method comprises applying electromagnetic radiation to a skin surface of an individual in a first treatment session to at least reduce damage to the skin caused by exposure of the individual to a source of Xray or ultraviolet radiation. The applying of the electromagnetic radiation to the skin surface is effectuated prior to, during or after the exposure of the individual to the source of Xray or ultraviolet radiation. The applying of the electromagnetic radiation to the skin surface is effectuated in the absence of any visible undesirable condition along the skin surface. Without detection of any substantial visible change in the skin surface, electromagnetic radiation is subsequently applied in a second treatment session to the skin surface to at least reduce damage to the skin caused by exposure to Xray or ultraviolet radiation. The electromagnetic radiation applied in the first treatment session and the second treatment session is characterized by parameters including pulse duration,

wavelength and total energy so selected that the applying of the electromagnetic radiation collectively promotes healthy skin and generates no visible damage such as tanning.

Applicant respectfully traverses the rejection of claim 1 as being unpatentable over Chubb in view of Eckhouse.

Chubb is directed to a method of controlling daily exposure to UVB radiation for purposes of achieving an even or temporally uniform production of vitamin D by the individual's skin throughout the year. The Eckhouse reference is directed to a process for removing hair and treating visibly undesirable dermatological disorders. Eckhouse targets melanin in the follicles below the epidermis. Eckhouse says nothing about treating skin for reducing skin damage caused by exposure to a source of Xray or ultraviolet radiation.

One skilled in the art would not consider using the pulsed source of Eckhouse in carrying out the method of Chubb. The pulsed source of Eckhouse is designed for specific applications inapposite to Chubb's method.

Chubb's purpose is to provide methods and apparatus to ensure that the individual has proper amounts of vitamin D throughout the year, this purpose being attained by controlling exposure to UVB radiation (the only radiation of the electromagnetic spectrum that is conducive to the production of vitamin D). Chubb's method entails a reduction in the exposure of the individual to sunlight during the summer and increased exposure of the individual to artificial sources of UVB radiation during the winter months.

The method of Eckhouse entails the application of pulsed light to destroy microscopic cellular structures such as hair follicles and blood vessels. Pulsed light is

used because it is particularly effective in producing selective absorption in such structures. Shorter wavelengths such as UVB radiation's 290-320 nm are ineffective because they do not effectively penetrate to the dermis where Eckhouse's target structures are located. A preferred embodiment of the Eckhouse light source delivers radiation primarily in the band 550-1300 nm. One skilled in the art would be motivated ***not*** to use the pulsed radiation of Eckhouse in the method of Chubb because the method of Chubb does not target the microscopic structures such as hair follicles and blood vessels for which pulsed light is designed.

Thus, one skilled in the art would not use a pulsed light source in the method of Chubb even if that light source produces UVB radiation. Chubb discloses the use of a lamp in the bathroom (col. 15, line 54) or bedroom (col. 30, line 2), particularly a wall-mounted quartz halogen lamp to provide UVB, during periods of reduced exposure to natural sunlight. Exposure of large areas of skin to such a light source is sufficient to increase levels of skin-manufactured vitamin D. There is no reason to use a pulse light source in the method of Chubb.

The reasoning provided by the Examiner in this respect is specious. The Examiner maintains, "Pulsing radiation is a well known technique that allows fluence levels to be controlled by altering the radiation parameters." The control of fluence levels is not the reason behind the use of pulsed radiation in skin treatment applications. Instead, as indicated above, pulsed radiation facilitates the targeting and destruction of specific skin structures and the sparing of other structures that are not targeted. Moreover, there is no reason to provide pulsing for controlling fluence in the method of Chubb when other techniques are readily available. The Chubb reference itself discloses

at least two basic techniques for controlling the amount of UVB radiation an individual receives: varying the time of exposure and the amount of skin area exposed. Another obvious technique is merely varying the power or wattage of the UVB source to produce more intense UVB radiation.

The pulsed light source of Eckhouse is adapted particularly for treating skin to ***selectively eliminate*** fine structures such as hair follicles and blood vessels. Such a light source would be inappropriate in the method of Chubb. There are no specific microstructures to be selectively destroyed by Chubb's method. Use of such a light source would be wasteful and unreasonably burdensome at best or potentially dangerous. The light source of Eckhouse applies pulsed light to such a small skin area that one would have to either apply a lot of light to a small surface area, potentially dangerous to the skin, or move the light source over a large area, which is burdensome and unnecessary given that the simpler method of Chubb is adequate.

One of ordinary skill in the art would simply not use a pulsed-radiation lamp in the method of Chubb. Pulsed light is designed for different skin-treatment applications, inapposite to the method of Chubb, and provides no benefits relative to the techniques of Chubb. The Examiner's citation of Eckhouse is an application of hindsight. There is nothing in the prior art that would lead one to apply the pulsed-light techniques of Eckhouse to the vitamin-D enrichment method of Chubb.

Dependent Claim 6 Regarding claim 6, the Examiner states (O.A. page 8) that the use of mini-pulses or pulse packets is not disclosed to yield specific benefits or unexpected results. The Examiner further states that one of ordinary skill in the art would have expected any pulse regimen that provides the dosage required to perform equally

well as they all provide the radiation to the skin as required. Applicant contravenes these statements inasmuch as applicant has disclosed that the use of multiple passes is safer, as involving lower energy fluences per pulse packet. Thus, not all pulse regimens perform equally well. In addition, it is believed that pulse packets with shorter pulse durations are more effective with small target bodies while pulses of longer duration are more effective with relatively larger target structures. Accordingly, it would not have been obvious to modify the teachings of the Chubb reference in view of Eckhouse to obtain the invention as set forth in claim 6. That invention is not a mere design consideration but provides a real benefit.

Similar observations apply to the Examiner's remarks concerning claims 7 and 8.

The Examiner remarks on page 9 of the Office Action that it "is also not clear how exposure to X-ray or UV radiation between the treatments (intervals of 24 hours) could be controlled as the UV radiation is pervasive in our environment, i.e., sunlight, fluorescent lights, etc." Applicant is not attempting to control the exposure to the X-ray or UV radiation. Rather applicant's invention is directed to treating people for their exposure to X-ray and UV radiation. Applicant teaches that the treatment is preferably within 24 hours of the exposure. Treatment after the exposure is straightforward as to timing. Treatment before exposure may involve some estimation of expected exposure in the case of sunlight. In other cases, such as tanning salons, the amount of exposure is generally predetermined and applicant's treatment can be measured out before the exposure. Standard fluorescent lights do not give off UV or X-ray radiation in any significant amounts.

Dependent Claims 16 and 17 Dependent claim 16 recites that the electromagnetic radiation applied to the skin surface per claim 1 has a wavelength absorbable by an endogenous chromophore in tissues along said skin surface. The Examiner states in rejecting this claim that Eckhouse teaches the absorption of light in the melanin in tissue. Applicant contravenes this statement inasmuch as Eckhouse targets hair follicles for purposes of permanently removing hair and selects wavelengths that penetrate through the tissue to the follicles. Thus the radiation is not about melanin in the skin but rather melanin in the hair follicles. Eckhouse's pulses would therefore not be suitable in Chubb's method. (The Examiner maintains that col. 21, lines 35 et seq., of Eckhouse teaches the absorption of light by melanin in the tissue. But Eckhouse more accurately talks about purposefully causing damage to the hair follicles in the dermis and sparing damage to tissue in the epidermis. Chubb's UVB is absorbed mainly in the epidermis. The two methods damage melanin at different levels of the skin.)

Dependent Claims 22, 23, 38, and 39 These claims recite the application of a marker film to every irradiated surface pursuant to applicant's claim 1. In rejecting these claims, the Examiner cites Talpalrui for leaving a marker trace on a skin surface. Applicant respectfully traverses this rejection. As discussed hereinafter with reference to claim 58, Talpalrui does not teach or suggest applying a marker film to the entire irradiated surface but instead leaves a line along the travel path of the irradiation instrument head. Moreover, Chubb does not apply a marker film and there is no reason to apply a marker film in the treatment method of Chubb. One sits below a UV lamp in a bathroom or bedroom. Is one to paint oneself to tell oneself that he has undergone the

Chubb daily regimen? It does not make sense to apply a marker film in the technique of Chubb.

As discussed above, one would not use the pulses of Eckhouse in the method of Chubb. Therefore, applying a marker film in the method of Eckhouse has no relevance to the method of Chubb.

Dependent Claims 25-28 The Examiner rejects dependent claims 25-28 as unpatentable over Chubb in view of Eckhouse and further in view of McDaniel. Applicant respectfully traverses this rejection. McDaniel uses an exogenous chromophore (claim 25), ultrasound energy (claim 27), and electromagnetic fields (claim 28) for different purposes than applicant. For instance, McDaniel uses ultrasound to increase skin permeability to a topical composition, while applicant uses ultrasound to reduce the incidence or likelihood of skin damage from ultraviolet or X-ray radiation.

Moreover, it would not have been obvious to use the exogenous chromophore, ultrasound energy, and electromagnetic fields of McDaniel in the method of Chubb. There is ***no*** indication in McDaniel or any other reference of record that an exogenous chromophore, ultrasound energy, or applied electromagnetic fields would ***assist in or enhance the production of vitamin D*** by the skin. One of ordinary skill in the art seeking to improve the method of Chubb would find ***no reason*** to use an exogenous chromophore, ultrasound energy, or an electromagnetic field.

The Examiner concludes that it would be useful to use the exogenous chromophore, ultrasound energy, and electromagnetic fields of McDaniel in the method of Chubb, but only because applicant has claimed an exogenous chromophore (claim 25),

ultrasound energy (claim 27), and electromagnetic fields (claim 28) in his method as set forth in claim 1.

Claim 68 For the reasons discussed above with reference to claim 1, one skilled in the art would not use the pulsed radiation generator of Eckhouse in the method of Chubb inasmuch as the pulsed radiation of Eckhouse is designed to target specific microscopic structures such as hair follicles not relevant to the method of Chubb. Using the pulsed light source and applicator of Eckhouse would be inappropriate in the method of Chubb, where the light sources provided by Chubb are easier and safer to use and more than adequate for Chubb's purposes and where the pulsed light source of Eckhouse would be burdensome or dangerous. Accordingly, applicant's method as set forth in claim 68 is patentable over the prior art of record.

As set forth in claim 68, a skin treatment method comprises periodically applying, in temporally spaced treatment sessions, electromagnetic radiation to a skin surface of an individual to at least reduce damage to the skin caused by exposure of the individual to Xray or ultraviolet radiation. The electromagnetic radiation is applied to the skin surface in each of the treatment sessions prior to, during or after the exposure of the individual to Xray or ultraviolet radiation. The electromagnetic radiation is applied to the skin surface in the absence of any visible Xray or ultraviolet light damage along the skin surface. (See specification paragraph bridging pages 12 and 13: applicant's prophylactic skin treatment method is particularly directed to the treatment of ***ostensibly undamaged*** or preclinically damaged skin.) The electromagnetic radiation is characterized by parameters including pulse duration, wavelength and total energy so selected that the

applying of the electromagnetic radiation promotes healthy skin and generates no visible damage such as tanning.

None of the references relied on by the Examiner discloses or suggests a method of applying electromagnetic radiation to ***reduce the incidence or likelihood of skin damage caused by exposure*** to a source of Xray or ultraviolet radiation. None of the references of record discloses or suggests the application of ***pulsed electromagnetic radiation*** to a skin surface in the absence of any Xray or ultraviolet radiation damage along that skin surface, to promote the health of the skin and in the process generate no visible damage such as tanning.

With respect to claim 68, neither Chubb nor Eckhouse nor any of the other references relied on by the Examiner discloses or suggests the application of pulsed electromagnetic radiation to a skin surface in the absence of any Xray or ultraviolet radiation damage along that skin surface, to promote the health of the skin.

Claim 29 Applicant respectfully traverses the rejection of claim 29 under 35 U.S.C. § 103(a). Claim 29 distinguishes over the prior art relied on by the Examiner for the reasons discussed above with respect to claims 1 and 68. One skilled in the art would not use the pulse generator of Eckhouse in carrying out the method of Chubb because the pulsed light of Eckhouse is designed for targeting specific dermal structures not implicated in the method of Chubb, because the prior art reveals nothing about pulsed light that would improve the method of Chubb, and because pulsed light would complicate the method of Chubb and potentially endanger the users of the method. In the last respect it is to be noted that the method of Chubb is intended for use by individuals mainly in their homes, while the light source and method of Eckhouse is intended for use

by professionals on their patients. The dangers of pulsed light as taught by the prior art, particularly Eckhouse, militate against its use in the method of Chubb.

As set forth in claim 29, a prophylactic skin treatment method comprises (a) generating a predetermined number of pulses of electromagnetic radiation each having a predetermined electromagnetic spectrum, (b) applying the pulses of electromagnetic radiation to an individual's skin surface, the pulses having at least one predetermined pulse duration, and a predetermined total energy, (c) exposing the individual to Xray or ultraviolet radiation, the exposing of the individual to Xray or ultraviolet radiation occurring within a predetermined period of time of the applying of the pulses to the skin surface, and (d) at least in part owing to the applying of the pulses to the skin surface, reducing or preventing damage to the tissues of the skin surface arising from the exposing of the individual to Xray or ultraviolet radiation. The pulse duration and total energy are so selected that the applying of the pulses of electromagnetic radiation promotes health of the skin and generates no visible damage such as tanning.

Claim 29 is deemed to be patentable for reasons discussed above with reference to claim 1. In addition, none of the reference cited by the Examiner, whether viewed individually or collectively, either discloses or suggests the exposing of an individual to Xray or ultraviolet radiation ***within a predetermined period of time*** of applying of pulses of electromagnetic radiation to the skin surface. Chubb does not require that the individual receiving UVB exposure be subjected to a source of UV or Xray radiation such as sunlight within a predetermined time of receiving the UVB radiation. For all Chubb et al. care, the individual may be totally housebound, without any exposure to the potentially damaging effects of solar radiation. Thus, Chubb does not teach or suggest

that the individual be exposed to Xray or ultraviolet radiation within a predetermined period of time of applying of pulses of electromagnetic radiation to the skin surface.

Claim 73 Claim 73 has been amended to provide a better definition of a specific feature of applicant's invention. More particularly, claim 73 has been amended to recite that the applying of the electromagnetic radiation includes applying electromagnetic radiation more frequently with increasing frequency or intensity of exposure of the skin surface to Xray or ultraviolet radiation. (See page 15, first full paragraph of the specification, for support.)

As set forth in claim 73, a skin treatment method comprising applying an effective amount of electromagnetic radiation to a skin surface to reduce the incidence or likelihood of damage to the skin caused by exposure to Xray or ultraviolet radiation. The electromagnetic radiation is applied to the skin surface on at least one occasion prior to, during or after the exposure of the individual to Xray or ultraviolet radiation. The electromagnetic radiation is applied to the skin surface in the absence of any visible Xray or ultraviolet radiation damage along the skin surface. The electromagnetic radiation is applied to the skin surface within a predetermined interval of the exposure of the skin surface to Xray or ultraviolet radiation. The applying of the electromagnetic radiation includes applying electromagnetic radiation more frequently with increasing frequency or intensity of exposure of the skin surface.

Chubb, the only reference relied on by the Examiner in rejecting claim 73, teaches the application of ***increasing*** amounts of radiation with ***decreasing*** exposure of the individual to sunlight, or, conversely, decreasing amounts of radiation with ***increasing*** exposure of the individual to sunlight.

Under the method of Chubb, ***supplemental*** light would be provided only when the individual is not exposed to adequate levels of natural sunlight, primarily during winter months. In the present invention, the light applied is not supplemental or additive, but rather used to ***offset*** the damaging effects of UV light, especially during the summer. Applicant's prophylactic radiation is administered at opposing times and for opposite purposes relative to Chubb's supplemental light.

Claim 70 Applicant respectfully traverses the rejection of claim 70 as being anticipated by the Chubb reference.

As set forth in claim 70, a skin treatment method comprises, without regard to visible skin conditions along a skin surface of an individual, applying electromagnetic radiation to the skin surface in a first treatment session to reduce the incidence or likelihood of damage to the skin caused by exposure of the individual to Xray or ultraviolet radiation, and subsequently, without regard to visible skin conditions along the skin surface, applying electromagnetic radiation to the skin surface in a second treatment session to reduce the incidence or likelihood of damage to the skin caused by exposure of the individual to Xray or ultraviolet radiation. The electromagnetic radiation applied to the skin surface during at least one of treatment sessions has an electromagnetic spectrum including only wavelengths greater than 400 nm.

Chubb, the only reference relied on by the Examiner in rejecting claim 70, requires the application of radiation with wavelengths below 400 nm in their methods. In particular, Chubb requires the application of UVB radiation, which has a wavelength range of 290-320 nm. Chubb is interested in even vitamin D production throughout the year. When Chubb applies light to the skin, it is for the purpose of enhancing the

production of vitamin D in the skin. UVB radiation is the ***only*** radiation that triggers or induces the production of vitamin D. Whenever Chubb applies electromagnetic radiation to a skin surface in a treatment session, the electromagnetic radiation must include UVB wavelengths. Otherwise, the purpose of Chubb would not be achieved. The method of Chubb would not work if the applied electromagnetic radiation had an electromagnetic spectrum including only wavelengths greater than 400 nm.

Those skilled in the art are well aware of the relationship between UVB radiation and vitamin D production. Chubb is rife with references to UVB radiation. Chubb refers to UVB at column 2, line 65, through col. 3, line 4. See also Chubb, col. 3, lines 20-23 and 44-46; col. 4, lines 43-44, 53-55, and 62-63, etc.

The Examiner states that the "condition of the skin is irrelevant to Chubb et al., in that the level of vitamin D is the primary concern, thereby implying any skin condition may be exposed, including damaged or undamaged." As pointed out above, Chubb does not imply anything of the sort and, on the contrary, explicitly states that certain skin conditions are inappropriate for treatment by UVB radiation. As set forth in col. 22, lines 40 et seq., of the Chubb reference, "There are certain skin conditions in which the application of ultraviolet radiation may lead to an exacerbation. These include the acute onset of psoriasis, acute eczema, lupus erythematosus, herpes simplex, and xeroderma pigmentosum."

The Examiner states that the method of Chubb includes daily exposure to light between 0.02 and 0.2 minimal erythma dose (MED). This is not accurate. The range is between 0.06 and 0.2 MED. The 0.02 value refers a whole body amount, while the 0.2 value refers to a 10% skin area exposure.

Claim 72 Applicant respectfully traverses the rejection of claim 72 and continues to assert that claim 72 distinguishes over the prior art. As set forth in claim 72, a skin treatment method comprises determining a degree of exposure of a skin surface to Xray or ultraviolet radiation, and subsequently applying an effective amount of electromagnetic radiation, in accordance with the determined degree of Xray or ultraviolet exposure, to a skin surface to at least reduce the incidence or likelihood of damage to the skin caused by exposure to the Xray or ultraviolet radiation, the applying of the electromagnetic radiation being effectuated in the absence of any visible Xray or ultraviolet radiation damage along the skin surface.

Chubb, the only reference asserted by the Examiner against claim 72 neither discloses nor suggests such a method wherein one determines a degree of exposure of a visibly undamaged skin surface to Xray or ultraviolet radiation and subsequently applies an effective amount of electromagnetic radiation to the skin surface, in accordance with the determined degree of Xray or ultraviolet exposure, to at least reduce damage to the skin caused by exposure to the Xray or ultraviolet radiation.

The Examiner particularly contends (page 6 of the Office Action) that "in the determination of a persons vitamin D levels, a determination of exposure to sunlight (contains both X-ray and UV) that produces the vitamin is inherent."

The Examiner's contention is patently mistaken. Vitamin D levels are affected not only by the incidence of UVB radiation on the individual's skin but also by diet. Good food sources are oily fish and eggs. Other food sources include fortified foods such as margarine, breakfast cereals, bread and powdered milk. The fortification of milk with vitamin D is particularly well known. Accordingly, a measurement of an individual's

vitamin D levels can provide no useful information about the exposure levels of the individual to Xray or ultraviolet radiation.

The Examiner also points out that Chubb discloses a meter (col. 26, line 55) for measuring ultraviolet radiation. However, Chubb discloses that this meter is used to measure UV radiation being transmitted through a window, for purposes of enabling one to adjust the amount of light (particularly UVB) being transmitted through the window. Chubb says nothing about measuring a degree of exposure of a skin surface to Xray or ultraviolet radiation, and subsequently applying an effective amount of electromagnetic radiation, in accordance with the determined degree of Xray or ultraviolet exposure.

Claim 58 Applicant traverses the rejection of claim 58 as being unpatentable over the teachings of Talpalrui.

As set forth in claim 58, a light treatment method comprises generating light of a selected spectral composition, directing the light towards a skin surface, and thereafter applying a marker film to the skin surface at locations where the light has been applied to the skin surface, the marker film being applied at each point of the skin surface to which the electromagnetic radiation has been applied.

Talpalriu teaches the application of a narrow strip or band of a marker to a skin surface. The marker manifestly does not cover the entire skin surface to which radiation has been applied. Instead, the marker is applied along only a narrow portion of the skin surface as a sign that radiation has been applied.

In rejecting claim 58 as unpatentable over Talpalrui, the Examiner merely considers it "obvious" marker film being applied at each point of the skin surface to which the electromagnetic radiation has been applied, even though Talpalrui clearly

teaches the application of a marker film only along a line that extends parallel to the direction of movement of the light applicator. Talpalrui provides no reason to extend the line of marker film to cover an entire area. Indeed, there are reasons for not applying marker film to an entire skin surface. For instance, the application of marker film to an entire surface entails an increase in costs for the use of more dye.

Applicant has provided a reason to apply marker film over the entire surface to which light has been applied, that is, to block the further application of radiation to the treated skin surface, where the marker film is opaque to the applied radiation, or to partially block incoming radiation, to limit the amounts that are applied after a first pass. Talpalriu provides no suggestion of applying the marker film in the way recited by applicant in amended claim 58.

Dependent Claim 59 Claim 59 has been amended herein to recite that the marker film of claim 58 is opaque. Talpalrui does not mention an opaque dye. In addition, at least one of Talpalrui's embodiments would not function if adapted to apply an opaque marker film to an entire surface. In the embodiment of Figures 10 and 11, the marker film is applied via a roller through which light passes. If an opaque marker film were applied to over the entire roller, the light could be blocked from reaching the skin surface.

New Dependent Claims 100-102 New dependent claims 100 through 102 identify particular embodiments of the method of claim 58, where multiple marker films are applied to a skin surface to mark respective passes of a radiant-energy-application device over the skin surface. Talpalrui says nothing about multiple passes over the same

skin surface. Support for these amendments is found in the paragraphs at the bottom of page 21 and the top of page 22 of the specification as filed.

New Dependent Claims 103 and 104 New dependent claims 103 recite that the applying of the marker film in claim 58 includes using a non-contact applicator such as a nozzle or an atomizer. Talpalrui discloses only contact applicators such as a roller and a marker tip or stylus. As soon as the Talpalrui applicator (light and marker film) is lifted from the skin surface, the marker film can no longer be applied to the skin surface **along** the path of light application. Pursuant to applicant's invention, a non-contact method of film application is much more conducive to applying film over an entire area of a treated skin surface, where the skin surface is not a smooth and even surface but has obstacles.

Claim 78 Applicant respectfully traverses the rejection of claim 78 as being unpatentable over Chubb in view of Eckhouse. For the reasons discussed above *inter alia* with reference to claims 1 and 68, one skilled in the art would ***not*** use the pulse generator of Eckhouse in the method of Chubb. Accordingly, applicant's method as set forth in claim 78 is patentable over the prior art of record.

Applicant traverses the rejection of claim 78 herein and contends that claim 78 distinguishes over the prior art. As set forth in claim 78, a skin treatment method comprising applying electromagnetic radiation to a skin surface of an individual to at least partially reduce the incidence or likelihood of damage to the skin caused by exposure of the individual to Xray or ultraviolet radiation, the applying of the electromagnetic radiation to the skin surface being effectuated prior to, during or after the exposure of the individual to Xray or ultraviolet radiation. The electromagnetic radiation is so defined by parameters including total energy, pulse number, pulse duration, and

electromagnetic spectrum, that the electromagnetic radiation is absorbed by endogenous chromophores in the epidermis and by chromophores in underlying tissues, to thereby stimulate a healing response and a release of tissue substances without permanently damaging the epidermis and the underlying tissues.

Chubb is directed to regulating the entire amount of UV radiation that impinges on a person throughout the year. The Chubb method requires the use of UV lamps in the winter time and sunscreens in the summer months. This is quite different from applicant's method of applying electromagnetic radiation.

Again, one skilled in the art would **not** consider using the pulsed source of Eckhouse in carrying out the method of Chubb. The pulsed light of Eckhouse is designed for targeting specific dermal structures not implicated in the method of Chubb In addition, the prior art reveals nothing about pulsed light that would improve the method of Chubb. Furthermore, a pulsed light source as described by Eckhouse would complicate the method of Chubb and potentially endanger the users of the method, if those users are unskilled in the use of such sophisticated and powerful medical devices. The pulsed light source of Eckhouse is designed for use by licensed professionals and could be dangerous if used in the home based method of Chubb.

Claim 90 Applicant respectfully contravenes the Examiner's rejection of claim 90 as unpatentable over Talpalrui in view of Eckhardt. The Examiner finds that the claimed invention is obvious merely because the apparatus of Eckhardt "is capable of detecting reflectance of a marker dye or film." While such a rejection may be appropriate for an apparatus claim, where functional limitations are irrelevant, the rejection is ***inappropriate*** for a ***method*** claim such as claim 90. Capability of performing an action is

not the same as doing that action. One skilled in the relevant art would have to experience inventive activity to arrive at applicant's claimed method from the teachings of Talpalrui and Eckhardt. One skilled in the art would plainly require some motivation or suggestion. The Examiner's rejection smacks of hindsight.

Claim 90 has been amended to recite that the marker film is invisible, i.e., is of a visually undetectable composition. This is the reason for the use of a sensor in detecting the marker film. In applicant's method, if the marker film has a visible pigment, then it may be detected visually without the need for a sensor.

According to claim 90, a light treatment method comprises generating energy of a selected composition, directing the energy towards a skin surface, thereafter applying a marker film of a visually undetectable composition to the skin surface at locations where the energy has been applied to the skin surface, and operating a sensor to detect the marker film on the surface.

Talpalrui teaches a marker film that is transparent but is provided with a visually detectable pigment. Eckhardt likewise uses visible films. There is nothing in Eckhardt to suggest that the marker film of Talpalrui could be invisible and detected with the aid of a sensor.

To the extent that the Examiner's rejection of dependent claim 81 applies to claim 90, applicant respectfully traverses the rejection of claim 81 and maintains that independent claim 90 and dependent claims 81-83 present subject matter that distinguishes over the prior art and particularly over the teachings of Talpalriu and Eckhardt.

As indicated in the immediately prior Amendment, one skilled in the art would not be motivated to use the sensors of Eckhardt in the method of Talpalriu. Talpalriu teaches the application of a narrow strip or band of a marker to a skin surface, along only a narrow portion of the skin surface as a sign that radiation has been applied. Eckhardt discloses the use of sensors in three applications, including (1) measuring light applied during a sterilization or disinfection operation in order to enable termination of light application once a predetermined amount of light has been applied. (Col. 9, lines 20-29.) This use of a sensor measures light directed to a skin surface but would not incline one of ordinary skill in the art to use the sensor to detect a marker film on a skin surface. That this light sensor of Eckhardt is ***capable*** of measuring reflectance from a marker film on a skin surface, as determined by the Examiner in a hindsight review of Eckhardt, does not make applicant's method steps obvious from Eckhardt and Talpalrui. Any photocell used in any application may be capable of detecting reflected light. That does not make any use of a photocell to detect reflected light obvious.

The Eckhardt reference also teaches (2) the use of an electrical impedance-measuring sensor may be used to detect bare skin as opposed to a bandage. (Col. 13, lines 57-67.) One of ordinary skill in the art would receive no impetus from Eckhardt here to use a sensor to detect a marker film applied to a skin surface. (3) Also pursuant to Eckhardt, a photosensor may be used to detect a pattern such as a barcode or a hue on a bandage for purposes of determining the transmissivity of the bandage. (Col. 14, lines 4-14.) Again, one of ordinary skill in the art would find no reason or motivation in these teachings to use the photosensor to detect a marker film on a skin surface. A marker film is not a bandage. One skilled in the art familiar with the teachings of Talpalrui and

Eckhardt would not be inclined to point the sensor of Eckhardt toward a skin surface that has been marked with a film but has no bandage.

Neither Talpalrui nor applicant teaches or requires a bandage, a disinfecting or sterilization process, or a color-changing film, as taught by Eckhardt. Neither Talpalrui nor applicant is attempting to sterilize a skin surface of bacteria. Eckhardt is directed to different problems and different subject matter than Talpalrui and applicant.

Accordingly, dependent claims 81-83 and independent claim 90 present additional subject matter that distinguishes over the prior art.

Information Disclosure Statement Pursuant to the Duty to Disclose under 37 C.F.R. §1.56(a), applicant encloses herewith a copy of Citation Form PTO-1449 listing patent documents relevant to the background of the invention described and claimed in the above-identified application. Also enclosed are copies of the listed documents.

It is to be noted that not all of the enclosed documents qualify as prior art to the instant application. The non-prior-art documents are listed to ensure consideration for purposes other than patentability under 35 U.S.C. §§ 102 and 103.

Pursuant to 37 C.F.R. § 1.97(e), the undersigned hereby certifies that none of the references cited on enclosed Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application. Also pursuant to 37 C.F.R. § 1.97(e), the undersigned further certifies, based on knowledge and belief of the undersigned, that none of the enclosed references was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing date hereof.

Dependent claims not specifically argued herein are patentable in part because their respective independent claims are patentable. Concomitantly, the rejections of the dependent claims are moot in view of the amendments and arguments presented herein.

Conclusion

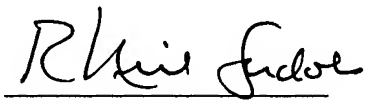
For the foregoing reasons, independent claims 1, 29, 58, 68, 70, 72, 73, 78, and 90, as well as the claims dependent therefrom, are deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

The claim amendments, if any, made herein are made without prejudice to applicants' right to pursue additional subject matter in a separate continuation or divisional application.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

COLEMAN SUDOL SAPONE, P.C.

By: 

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